

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 (Amended after Comments)

4 900 KAR 5:020. State Health Plan for facilities and services.

5 RELATES TO: KRS 216B.010-216B.130

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28)

7 [216B.015(27)], 216B.040(2)(a)2a

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)2.a requires
9 the cabinet to promulgate an administrative regulation, updated annually, to establish
10 the State Health Plan. The State Health Plan is a critical element of the certificate of
11 need process for which the cabinet is given responsibility in KRS Chapter 216B. This
12 administrative regulation establishes the State Health Plan for facilities and services.

13 Section 1. The 2013-2015 [2012][2011] ~~Update to the 2010-2012~~ State Health Plan
14 shall be used to:

- 15 (1) Review a certificate of need application pursuant to KRS 216B.040; and
16 (2) Determine whether a substantial change to a health service has occurred
17 pursuant to KRS 216B.015 (29) [~~(28)~~](a) and 216B.061(1)(d).

18 Section 2. Incorporation by Reference. (1) The "2013-2015 [2012][2011] ~~Update to~~
19 ~~the 2010-2012~~ State Health Plan", February 2013 [November 2012][May 2011], is
20 incorporated by reference.

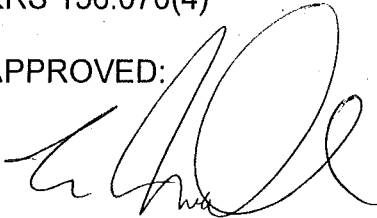
- 21 (2) This material may be inspected, copied, or obtained, subject to applicable

- 1 copyright law, at the Office of Health Policy, 275 East Main Street, 4WE [fourth floor],
- 2 Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.900 KAR 5:020.

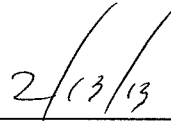
900 KAR 5:020

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

APPROVED:

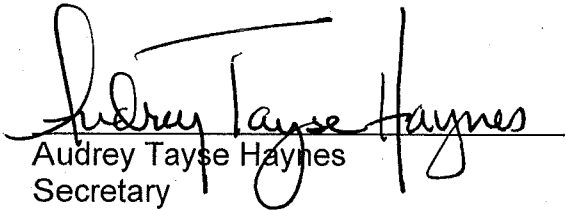


Eric Friedlander
Acting Executive Director
Office of Health Policy

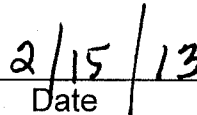


Date

APPROVED:



Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services



Date

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Diona Mullins or Chandra Venettozzi

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation incorporates by reference 2013-2015 State Health Plan, revised February 2013. The 2013-2015 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), 216B.040(2)(a)2a.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of 216B.010-216B.130 by incorporating by reference the 2013-2015 State Health Plan, revised February, 2013. The 2013-2015 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a. KRS 216B.015(28) states the State Health Plan be prepared triennially and updated annually. This regulation incorporates by reference the 2013-2015 State Health Plan.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.040(2)(a)2.a by incorporating by reference the 2013-2015 State Health Plan.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment incorporates by reference the 2013-2015 State Health Plan.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary as KRS 216B.015(28) states the State Health Plan be prepared triennially and updated annually. This regulation incorporates the 2013-2015 State Health Plan.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by providing the 2013-2015 State Health Plan.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will provide 2013-2015 State Health Plan.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects entities wishing to file an application for a Certificate of Need. Approximately 160 entities file an application for a Certificate of Need each year.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities wishing to submit an application for a Certificate of Need will be subject to the revised criteria set forth in the revised 2013-2015 State Health Plan.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No cost will be incurred by regulated entities to comply with this regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities will now have revised criteria set forth in the revised 2013-2015 State Health Plan so that they make more accurately complete their application for a Certificate of Need.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No cost.

(b) On a continuing basis: No cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be from Office of Health Policy's existing budget. No additional funding will be required.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.

(9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation affects the Office of Health Policy within the Cabinet for Health and Family Services.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), 216B.040(2)(a)2a.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate any revenue in the subsequent years.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES

Office of Health Policy

900 KAR 5:020, State Health Plan for Facilities and Services

Summary of Changes to Material Incorporated by Reference

The 2013-2015 State Health Plan, revised February 2013 is being incorporated by reference. The 2013-2015 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a. The 2013-2015 State Health Plan includes revisions to the following:

- a. There were various formatting changes made throughout the document that did not change the content.
- b. The introductory page was changed to reflect the change in dates within the title from the 2012 Update to the 2010 – 2012 State Health Plan (November, 2012) to the 2013 – 2015 State Health Plan and revision date of February 2013.
- c. The Table of Contents on page ii was revised to reflect changes in page numbers as a result of content changes in the document.
- d. Page iii, first paragraph was revised to correctly reference the 2013 – 2015 State Health Plan and to correctly reference statute KRS 216B.015(29).
- e. Page iii, second paragraph was revised to correctly reference statute KRS 216B.015(28).
- f. Page iii, item 1 under technical notes, was revised for clarity.
- g. Page iii, new item 2 was inserted to add language clarifying that only counties located within Kentucky are considered in the geographic area for review. Subsequent items were renumbered.
- h. Page iii, item 4 (now item 3) was revised to add the web site where utilization reports are available and the phone number to contact the Office of Health Policy.
- i. Page iv, item 5 (now item 6) was revised to remove reference to “acute”.
- j. Page iv, item 8 (now item 9) was revised to delete reference to Kentucky Annual Magnetic Resonance Imaging Services Report and a secondary phone number for OHP.
- k. Page iv, item 11 (now item 12) was revised to delete reference to PET/CT scanner.
- l. Page 1, first paragraph under definitions, 6th line, after “Division of Health Care” delete “Facilities”.

- m. Page 2, first line, revised to indicate the correct symbol for multiplication.
- n. Page 7, description for "PD" was revised to indicate beds "statewide".
- o. Page 9, item 5 was revised to clarify the most recent edition of the American Academy of pediatrics and the American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care is used.
- p. Page 9, item 6 was revised to change the reference from "their" to "the".
- q. Page 10, item 6 d was revised to clarify obstetricians and neonatologists may be on site or able to be present on the unit.
- r. Page 10, item 6 f was revised to clarify that personnel have specialized training in neonatal care.
- s. Page 10, a new item 7 was added to provide review criteria to be used when reviewing an application from an applicant for Level II special care neonatal care beds that will provide care for stable or moderately ill newborn infants who are born at ≥ 28 weeks gestation, or who weigh ≥ 1200 grams at birth, or require ventilation for > 24 hours. The criteria includes establishment of a relationship through a written affiliation agreement with a Level IV facility and the requirements to be included in that agreement, requirement to participate in the Vermont-Oxford Network (VON), demonstrate readily available pediatric ophthalmology services, and consultation from a maternal-fetal medicine specialist. Subsequent items were renumbered.
- q. Page 10, item 7 (now item 8) is revised to clarify notwithstanding only criterion 1 above.
- r. Page 10, item 2 under Level III criteria is revised to clarify the most recent edition of the American Academy of pediatrics and the American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care is used.
- s. Page 11, item 3 b under Level III criteria is revised to clarify neonatologists and personnel have specialized training in neonatal care and be on-site and available 24 hours per day.
- t. Page 11, item 3 c under Level III criteria is reworded for clarification.
- u. Page 11, item 3 j under Level III criteria clarifies the VON report on outcomes of Level III facility is submitted to the Cabinet.
- v. Page 11, new item k was added to clarify that an applicant proposing to establish Level III services requires the establishment of a relationship through a written affiliation agreement with a Level IV facility and the requirements to be included in that agreement.
- w. Page 12, item 4 under Level III is revised to clarify notwithstanding only criterion 1 above.
- x. Page 12, item 5 under Level III is revised to clarify notwithstanding only criteria 1 and 4 above.

- y. Page 12, item 1 under Level IV is revised to clarify the applicant must be an academic medical center or a children's hospital with a pediatric and neonatal training program that is accredited by the American College of Graduate Medical Education.
- z. Page 12, item 3 under Level IV is revised to eliminate reference to an example.
- aa. Page 12, new item 6 is added to clarify the responsibilities of the Level IV facility within the written affiliation agreement with the Level II facility.
- ab. Page 12, new item 7 was added to clarify that the Level IV facility will enter into a written affiliation agreement with the Level III facility.
- ac. Page 12, new item 8 was added to clarify the commitments required of the Level IV facility.
- ad. Page 14, item 1 g last sentence was deleted.
- ae. Page 16, a new definition for "Allocate psychiatric beds" was added.
- af. Page 19, first paragraph under Geriatric Psychiatric Services was revised to include critical access hospitals.
- ag. Page 20, item 1 was revised to clarify reference to acute care hospital.
- ah. Page 20, item 2 was revised to clarify reference to acute care hospital.
- ai. Page 20, item 3 was revised to remove language related to converted beds and remove reference to acute care.
- aj. Page 20, item 4 was revised to remove reference to converted beds.
- ak. Page 20, item 5 was revised to reference applicant rather than hospital.
- al. Page 20, item 7 was revised to reference geriatric psychiatric rather than converted beds.
- am. Page 28, definition of Energy Employees Occupational Illness Compensation Program was deleted.
- an. Page 28, first paragraph under Summary of Need Criteria, the last sentence related to EEOICPA was deleted.
- ao. Page 28, second paragraph under Summary of Need Criteria, the last sentence related to EEOICPA was deleted.
- ap. Page 29, item 4 is deleted.
- aq. Page 35, definition of Cardiac Catheterization, second sentence related to a single procedure was deleted.

- ar. Page 35, definition of Cardiac Catheterization, in third sentence, after "cardiac Catheterization" insert procedures.
- as. Page 35, in the entirety of section "A. Cardiac Catheterization Service", all references to *Annual Administrative Claims Data Report* have been changed to *Annual Administrative Claims Data Report – Cardiac Catheterization*.
- at. Page 36, item 1 a. is revised to delete reference to Facilities.
- au. Page 36, item 2 is revised to insert "and elective" after "(i.e. emergency)".
- av. Page 37, item 2 b, deleted all information after "during the previous two (2) years".
- aw. Page 37, item 2 c was deleted and subsequent subsections were renumbered.
- ax. Page 37, item 2 g (now 2 f) was revised to add unstable angina, and angina that is refractory to medical treatment at the end of the sentence.
- ay. Page 38, item 2 k (now 2 j) was revised to add references to located on-site or based at a facility and added reference that the program director must have performed a minimum of 150 PCI procedures in the previous year.
- az. Page 38, item 2 l (now 2 k) was added to state cardiologist on-site must be board certified by the American board of Internal Medicine in interventional cardiology.
- ba. Page 38, item 2 m i was revised to add "and elective" after "have received primary".
- bb. Page 38, new item 2 n was added to clarify the actions required at the end of the two (2) year trial related to verification of quality of the program.
- bc. Page 38, all of existing item 3 was deleted and subsequent sections were renumbered.
- bd. Page 40, item 4 (now item 3) first sentence was reorganized with subsections a and b for clarity. This necessitated existing subsections a through d being renumbered to i through iv.
- be. Page 40, item 4 a (now item 3 b i) is revised to clarify the applicant must have previously completed the two (2) year pilot for primary and/or elective PCI and have completed the requirements of 900 KAR 6:120.
- bf. Page 40, item 4 b (now item 3 b ii) is revised to clarify the applicant must submit verification of quality as specified in criterion 2.n. above.
- bg. Page 40, item 4 c (now item 3 b iii) is revised to reference item 3.b.iv rather than 4 d.
- bh. Page 40 Item 4 d (now item 3 b iv) is revised to reference the most recent edition of the Administrative Claims Data Report and an average of at least three hundred (300) annual diagnostic cardiac catheterization procedures.
- bi. Page 41, new item 3 b v was added to clarify the applicant will maintain a signed collaboration agreement with a tertiary hospital and what the agreement shall address.

- bj. Page 42, item 6 (now item 5) was revised to reference Level IV rather than Level III.
- bk. Page 56, item 3 was revised to add language that notwithstanding the above criteria and the application must demonstrate the proposed services is not currently provided by another licensed home health agency or private duty nursing service provider.
- bl. Page 56, item 4 was revised add language that notwithstanding the above criteria and the application must demonstrate the proposed services is not currently provided by another licensed home health agency or private duty nursing service provider.
- bm. Page 57, reference to Attachment A is deleted, and the attachment is deleted.

STATEMENT OF CONSIDERATION RELATING TO 900 KAR 5:020

Office of Health Policy
Amended after comments

- (1) A public hearing on 900 KAR 5:020 was held on 12/21/2012 at 9:00 a.m. Comments were received during the public hearing and written comments were received.

- (2) The following people submitted comments during the public hearing:

<u>NAME AND TITLE</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Kip Bomar Executive Director	Kentucky Home Care Association
Brian W. Lebanon Secretary	Professional Home Health Care Agency, Inc.

- (3) The following people submitted written comments via the public comment process:

<u>NAME AND TITLE</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Nancy Galvagni Senior Vice President	Kentucky Hospital Association
Andy Sears Vice President Planning and System Development	Baptist Health System, Inc.
Kelly Elkins	KentuckyOne Health
Kevin B. Halter, FACHE Chief Executive Officer	Our Lady of Bellefonte Hospital
Khaldon Jundi, MD, FAAP	Bluegrass Newborn Specialists, PLC.
Chip Peal Chief Executive Officer	Frankfort Regional Medical Center
Alex Soriano, MD President	Neonatal Services, PSC
Walter E. May President/CEO	Pikeville Medical Center

Russ Ranallo
Vice President of Financial Services

Owensboro Medical Health System

Bridget Burshears, MD, FAAP
Medical Director, NICU

Owensboro Medical Health System

Mahesh G. Naik, MD
Lynda P. Sanders, MD
John C. Vance, MD
Tonia L. Reid, MD

Pediatric Medical Group

Deborah Reed-Thurston, MD
(Referred to as Staff or Pediatric Medical Group)

Beth McCraw, APRN, ACNS-BC
Vice President of Nursing &
Clinical Services

Jennie Stuart Medical Center

Bradley W. Housman, MD

Western Baptist Hospital

Wade R. Stone
Vice President

The Medical Center

Bruce Begley, CEO, and
The Methodist Hospital Board of Directors

Methodist Hospital

John S. Dubis, FACHE
President and CEO

St. Elizabeth Healthcare

Dan L. Stewart, MD
Professor of Pediatrics

The Division of Neonatal Medicine of the
Dept. of Pediatrics at U of L

Heidi Schissler Lanham
Legal Director

Protection and Advocacy

Greg Austin, President
(Comments submitted by J. Wade Hendricks)

Professional Case Management

Marie Alagia Cull
Marian J. Hayden

Cull & Hayden, P.S.C.

Mary Jo Bean
Vice President, Planning

Norton Healthcare

- (4) The following people from the promulgating administrative body responded to the written comments:

NAME AND TITLE

Eric Friedlander
Diona Mullins

Acting Executive Director, Office of Health Policy
Policy Advisor, Office of Health Policy

SUMMARY OF COMMENTS AND AGENCY RESPONSE

- (1) Subject Matter: Provisions regarding Megavoltage Radiation Equipment program/population ratio in Criterion #1(c).
 - (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Andy Sears, on behalf of Baptist Healthcare Systems, Inc., Kevin Halter on behalf of Our Lady of Bellefonte Hospital, John Dubis on behalf of St. Elizabeth Healthcare, Wade Stone on behalf of The Medical Center, Chip Peal on behalf of Frankfort Regional Medical Center, and Kelly Elkins on behalf of KentuckyOne Health request that the program/population ratio set forth in Criterion # 1(c) be reinstated in the State Health Plan.
 - (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan to reinstate the program/population ratio set forth in Criterion # 1(c). The Cabinet's decision to eliminate Criterion #1 (c) addresses improved access to Megavoltage services.
- (2) Subject Matter: Provisions regarding Megavoltage Radiation Equipment to address improved access of services.
 - (a) Comment: Kelly Elkins, on behalf of the KentuckyOne Health requests that if the Cabinet makes changes in the Megavoltage Radiation Equipment component of the State Health Plan that one of KentuckyOne Health's two proposed alternatives be adopted to address the issue of improved access in counties that have substantial hospitals, but have no licensed radiation oncology facilities. Alternative #1 criterion addresses an entity with majority ownership by a 100 bed acute care hospital if there is no megavoltage program in the county. Alternative # 2 changes the average number of procedures performed in the planning area to 6,000 from 8,000.
 - (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan to include either of the proposed alternatives at this time as the removal of Criterion 1(c) will address, in part, the improved access to Megavoltage services.
- (3) Subject Matter: Provisions regarding Level II Special Care Neonatal Beds
 - (a) Comment: Nancy Galvagni, on behalf of Kentucky Hospital Association (KHA), Andy Sears, on behalf of Baptist Health System, Inc., Kelly Elkins, on behalf of KentuckyOne Health, Kevin B. Halter on behalf of Our Lady of

Bellefonte Hospital, Khaldon Jundi, MD on behalf of Bluegrass Newborn Specialists, PLC, Chip Peal on behalf of Frankfort Regional Medical Center, Alex Soriano, MD on behalf of Neonatal Services, PSC, Walter E. May on behalf of Pikeville Medical Center, Russ Ranallo and Bridget Burshears, MD on behalf of Owensboro Medical Health System, Staff of Pediatrix Medical Group, Beth McCraw, APRN, on behalf of Jennie Stuart Medical Center, Bradley W. Housman, MD, on behalf of Western Baptist Hospital, Wade R. Stone on behalf of The Medical Center, Bruce Begley and the Board of Directors on behalf of Methodist Hospital, John S. Dubis on behalf of St. Elizabeth Healthcare and Dan L. Stewart on behalf of the Division of Neonatal Medicine of the Dept. of Pediatrics at U of L request that the plan be revised to allow flexibility for a Level II facility to care for neonates that deviate from the specified weight and gestational age or the length of ventilation and/or CPAP contained in the Perinatal guidelines for Level II. Level II facilities would be required to enter into an affiliation agreement with a provider of Level IV services to address medical judgment regarding when an infant may be safely cared for in a Level II facility and when the infant should be transferred to a higher level of care. The recommendations were unanimously approved by KHA's Perinatal Subcommittee, KHA's Certificate of Need Committee, and the Executive Committee of the KHA Board.

(b) Response: The Cabinet has considered this request and will amend the State Health Plan to allow a Level II facility to care for stable or moderately ill neonates born at ≥ 28 weeks gestation or who weigh ≥ 1200 grams at birth if they document the ability to:

1. Participate in the Vermont-Oxford Network (VON) and supply outcomes reports to the Cabinet and a provider of Level IV services.
2. Establish a collaborative relationship approved by the Cabinet with a provider of Level IV services for purposes of maternal and neonatal transfer, training, clinical, expertise, and consultation.
3. Provide ventilation services restricted to conventional ventilation with the approval of the provider of Level IV services.
4. Provide the appropriate staff and equipment to treat these neonates.
5. Obtain consultation, on a 24 hour basis, from a maternal-fetal medicine specialist regarding management of high risk obstetric patients.

In addition, the Cabinet will revise the Level IV review criteria to address the responsibilities of the Level IV facilities regarding required affiliation agreements with Level II facilities and collection and analysis of VON outcomes reports.

(4) Subject Matter: Provisions regarding Level II Special Care Neonatal Bed need methodology.

(a) Comment: Nancy Galvagni, on behalf of Kentucky Hospital Association

(KHA), Andy Sears, on behalf of Baptist Health System, Inc., Kelly Elkins, on behalf of KentuckyOne Health, Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital, Khaldon Jundi, MD on behalf of Bluegrass Newborn Specialists, PLC, Chip Peal on behalf of Frankfort Regional Medical Center, Alex Soriano, MD on behalf of Neonatal Services, PSC, Walter E. May on behalf of Pikeville Medical Center, Russ Ranallo and Bridget Burshears, MD on behalf of Owensboro Medical Health System, Staff of Pediatrix Medical Group, Beth McCraw, APRN, on behalf of Jennie Stuart Medical Center, Bradley W. Housman, MD, on behalf of Western Baptist Hospital, Wade R. Stone on behalf of The Medical Center, Bruce Begley and the Board of Directors on behalf of Methodist Hospital, John S. Dubis on behalf of St. Elizabeth Healthcare and Dan L. Stewart on behalf of the Division of Neonatal Medicine of the Dept. of Pediatrics at U of L request deletion of the Plan's Level II bed need methodology and insert language specifying that the maximum number of Level II beds that can be approved be based on volume projected five years in the planning area from the date the application is filed. The recommendations were unanimously approved by KHA's Perinatal Subcommittee, KHA's Certificate of Need Committee, and the Executive Committee of the KHA Board.

- (b) Response: The Cabinet has considered this request and will not amend the State Health Plan to revise the existing Level II bed need methodology as a need methodology with a bed cap ensures there will not be an unnecessary proliferation of services.

(5) Subject Matter: Provisions regarding Level III Special Care Neonatal Beds

- (a) Comment: Nancy Galvagni, on behalf of Kentucky Hospital Association (KHA), Andy Sears, on behalf of Baptist Health System, Inc., Kelly Elkins, on behalf of KentuckyOne Health, Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital, Khaldon Jundi, MD on behalf of Bluegrass Newborn Specialists, PLC, Chip Peal on behalf of Frankfort Regional Medical Center, Alex Soriano, MD on behalf of Neonatal Services, PSC, Walter E. May on behalf of Pikeville Medical Center, Russ Ranallo and Bridget Burshears, MD on behalf of Owensboro Medical Health System, Staff of Pediatrix Medical Group, Beth McCraw, APRN, on behalf of Jennie Stuart Medical Center, Bradley W. Housman, MD, on behalf of Western Baptist Hospital, Wade R. Stone on behalf of The Medical Center, Bruce Begley and the Board of Directors on behalf of Methodist Hospital, John S. Dubis on behalf of St. Elizabeth Healthcare and Dan L. Stewart on behalf of the Division of Neonatal Medicine of the Dept. of Pediatrics at U of L request that the plan be revised to require a Level III facility to enter into a written affiliation agreement with a provider of Level IV services for the purposes of maternal and neonatal transfer, training, clinical expertise and consultation. The recommendation was unanimously approved by KHA's Perinatal Subcommittee, KHA's Certificate of Need Committee, and the Executive Committee of the KHA

Board.

- (b) Response: The Cabinet has considered this request and will amend the State Health Plan to require a Level III facility to establish a collaborative relationship, approved by the Cabinet, with a provider of Level IV services for the purposes of consultation, clinical expertise, education and training, and maternal and neonatal transfer. In addition, the Cabinet will revise the Level IV review criteria to address the responsibilities of the Level IV facilities regarding required affiliation agreements with Level III facilities and collection and analysis of VON outcomes reports.

- (6) Subject Matter: Provisions regarding Level III Special Care Neonatal Bed need methodology.

- (a) Comment: Nancy Galvagni, on behalf of Kentucky Hospital Association (KHA), Andy Sears, on behalf of Baptist Health System, Inc., Kelly Elkins, on behalf of KentuckyOne Health, Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital, Khaldon Jundi, MD on behalf of Bluegrass Newborn Specialists, PLC, Chip Peal on behalf of Frankfort Regional Medical Center, Alex Soriano, MD on behalf of Neonatal Services, PSC, Walter E. May on behalf of Pikeville Medical Center, Russ Ranallo and Bridget Burshears, MD on behalf of Owensboro Medical Health System, Staff of Pediatrix Medical Group, Beth McCraw, APRN, on behalf of Jennie Stuart Medical Center, Bradley W. Housman, MD, on behalf of Western Baptist Hospital, Wade R. Stone on behalf of The Medical Center, Bruce Begley and the Board of Directors on behalf of Methodist Hospital, John S. Dubis on behalf of St. Elizabeth Healthcare and Dan L. Stewart on behalf of the Division of Neonatal Medicine of the Dept. of Pediatrics at U of L request deletion of the Plan's Level III bed need methodology and insert language to allow an existing Level II facility to establish Level III beds by converting existing Level II beds to Level III beds without meeting criteria for "new" beds as long as the facility includes a description of need to support request. Need for Level III beds not converted from Level II beds would be demonstrated on a regional instead of a statewide basis and approval would be based on the applicant's reasonable forecast of utilization or a regression analysis progression of patient trends over a five year time frame. These recommendations were unanimously approved by KHA's Perinatal Subcommittee, KHA's Certificate of Need Committee, and the Executive Committee of the KHA Board.

- (b) Response: The Cabinet has considered this request and will not amend the State Health Plan to revise the Level III bed need methodology as a need methodology with a bed cap ensures there will not be an unnecessary proliferation of services.

- (7) Subject Matter: Provisions regarding Level II and Level III Special Care Neonatal Beds statewide participation is perinatal collaborative.

- (a) Comment: Nancy Galvagni, on behalf of Kentucky Hospital Association (KHA), Andy Sears, on behalf of Baptist Health System, Inc., Kelly Elkins, on behalf of KentuckyOne Health, Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital, Khaldon Jundi, MD on behalf of Bluegrass Newborn Specialists, PLC, Chip Peal on behalf of Frankfort Regional Medical Center, Alex Soriano, MD on behalf of Neonatal Services, PSC, Walter E. May on behalf of Pikeville Medical Center, Russ Ranallo and Bridget Burshears, MD on behalf of Owensboro Medical Health System, Staff of Pediatrix Medical Group, Beth McCraw, APRN, on behalf of Jennie Stuart Medical Center, Bradley W. Housman, MD, on behalf of Western Baptist Hospital, Wade R. Stone on behalf of The Medical Center, Bruce Begley and the Board of Directors on behalf of Methodist Hospital, John S. Dubis on behalf of St. Elizabeth Healthcare and Dan L. Stewart on behalf of the Division of Neonatal Medicine of the Dept. of Pediatrics at U of L requests that Level II and Level III facilities be required to participate in a statewide perinatal collaborative operated under the Kentucky Institute for Patient Safety and Quality (a PSO). These recommendations were unanimously approved by KHA's Perinatal Subcommittee, KHA's Certificate of Need Committee, and the Executive Committee of the KHA Board.
- (b) Response: The Cabinet has considered this request and will not amend the State Health Plan as requested because submission of outcomes data to a PSO does not allow public or State access to this data. Instead the Cabinet will amend the State Health Plan to require Level II facilities providing services to neonates born at ≥ 28 weeks gestation or who weigh ≥ 1200 grams at birth and Level III facilities to participate with the Vermont-Oxford Network and share data/outcomes with Level IV facility and the Cabinet.
- (8) Subject Matter: Provisions regarding Level IV Special Care Neonatal Bed need methodology.
- (a) Comment: Nancy Galvagni, on behalf of Kentucky Hospital Association (KHA), Andy Sears, on behalf of Baptist Health System, Inc., Kelly Elkins, on behalf of KentuckyOne Health, Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital, Khaldon Jundi, MD on behalf of Bluegrass Newborn Specialists, PLC, Chip Peal on behalf of Frankfort Regional Medical Center, Alex Soriano, MD on behalf of Neonatal Services, PSC, Walter E. May on behalf of Pikeville Medical Center, Russ Ranallo and Bridget Burshears, MD on behalf of Owensboro Medical Health System, Staff of Pediatrix Medical Group, Beth McCraw, APRN, on behalf of Jennie Stuart Medical Center, Bradley W. Housman, MD, on behalf of Western Baptist Hospital, Wade R. Stone on behalf of The Medical Center, Bruce Begley and the Board of Directors on behalf of Methodist Hospital, John S. Dubis on behalf of St. Elizabeth Healthcare and Dan L. Stewart on behalf of the Division of Neonatal Medicine of the Dept. of Pediatrics at U of L request revision of the plan's

Level IV review criteria to require 70% utilization of an existing Level IV unit before additional beds will be approved for the existing program and to require that the maximum number of beds that can be approved for an existing program or establishment of a new level IV program in the state be based on the applicant's reasonable forecast of utilization or a regression analysis progression of patient day trends over a five year time-frame. These recommendations were unanimously approved by KHA's Perinatal Subcommittee, KHA's Certificate of Need Committee, and the Executive Committee of the KHA Board.

(b) Response: The Cabinet has considered this request and will not amend the State Health Plan to include the requested need criteria. The Cabinet will amend the State Health Plan to require that an applicant for level IV beds shall be:

1. An academic medical center with a pediatric and neonatal training program that is accredited by the American College of Graduate Medical Education, or
2. A children's hospital with a pediatric and neonatal training program accredited by the American College of Graduate Medical Education.

(9) Subject Matter: Provisions regarding Special Care Neonatal Beds Level III review Criterion #5.

(a) Comment: Kelly Elkins, on behalf of KentuckyOne Health and Khaldon Jundi on behalf of Bluegrass Newborn Specialists request that the Cabinet amend review Criterion #5 to allow reclassification of a portion of Level II beds to Level III as follows:

"Notwithstanding the above criteria, applications proposing to convert up to fifty percent (50%) of existing Level II special neonatal beds, as published in the November 2012 Certificate of Need Inventory of Health Facilities and Services, to Level III special neonatal beds shall be consistent with the State Health Plan if the hospital is an in-state hospital with a Level II neonatal center which:

1. Has a minimum of 1,500 Medicaid neonatal Level II patient days per year;
2. Has a gestational age lower limit of twenty-seven (27) weeks; and
3. Has a full-time perinatologist on staff."

(b) Response: The Cabinet has considered this comment and will not amend the State Health Plan. The Cabinet will retain the current language that requires the facility be recognized as a "high intensity Level II neonatal center" pursuant to 907 KAR 10:825 to prevent an unnecessary proliferation of services.

(10) Subject Matter: Support for provisions regarding Special Care Neonatal Beds

Level III new review Criterion #5.

(a) Comment: Staff of Pediatrix Medical Group, Alex Soriano on behalf of Neonatal Services, and Andy Sears on behalf of Baptist Healthcare System request that the Cabinet maintain the new review criterion #5 for Level III Special Care Neonatal Beds.

(b) Response: The Cabinet has considered this comment and will not amend the State Health Plan as this recommendation is consistent with the existing language.

(11) Subject Matter: Criterion 1 in Level III related to need methodology.

(a) Comment: Khaldon Jundi on behalf of Bluegrass Newborn Specialists requests that the Cabinet remove review criterion 1 for Level III Special Care Neonatal Beds.

(b) The Cabinet has considered this comment and will not amend the State Health Plan as removal of a need methodology with a bed cap may result in an unnecessary proliferation of services.

(12) Subject Matter: Special Care Neonatal Beds Level II new review Criterion #6(f).

(a) Comment: Mary Jo Bean on behalf of Norton Healthcare requests that the Cabinet amend Level II review criterion 6(f) to explicitly state that these personnel should have specialized training in neonatal care.

(b) Response: The Cabinet has considered this comment and will amend the State Health Plan as requested.

(13) Subject Matter: Special Care Neonatal Beds Level III review Criterion #2 that was deleted.

(a) Comment: Mary Jo Bean on behalf of Norton Healthcare requests that the Cabinet reinstate the previously deleted review criterion 2 which stated: "The Cabinet determines that more Level III beds than indicated by the above calculation are justified in order to allow for the presence of hospitals that provide a higher intensity of neonatal care than that provided by most hospitals due to a high percentage of neonatal patient referrals for specialized services such as open heart surgery, transplants, etc."

(b) Response: The Cabinet has considered this comment and will not amend the State Health Plan. The Cabinet addressed the issue of hospitals providing a higher intensity of neonatal care by retaining the current language in Level III criterion # 5 that requires the facility be recognized as a "high intensity Level II neonatal center" pursuant to 907 KAR 10:825.

- (14) Subject Matter: Special Care Neonatal Beds Level III new review Criterion #3(b).
- (a) Comment: Mary Jo Bean on behalf of Norton Healthcare requests that the Cabinet amend review criterion 3(b) to clarify that these clinical specialties should be "on-site and available 24 hours per day".
 - (b) Response: The Cabinet has considered this comment and will amend the State Health Plan as requested.
- (15) Subject Matter: Special Care Neonatal Beds Level III new review Criterion #5.
- (a) Comment: Mary Jo Bean on behalf of Norton Healthcare requests that the Cabinet amend review criterion 5 to clarify that any criterion 5 applicant must also meet all subparts of new criteria 3(a) through (k) to ensure birth weight and gestational age considerations are consistent for all applicants.
 - (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to provide clarification as requested.
- (16) Subject Matter: Special Care Neonatal Beds Level IV new review Criterion #2.
- (a) Comment: Mary Jo Bean on behalf of Norton Healthcare requests that the Cabinet delete review criterion 2 as being unnecessary and redundant.
 - (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan as the language is necessary to ensure a Level IV facility provides all the services of a Level III facility.
- (17) Subject Matter: Provisions regarding Comprehensive Rehabilitation Beds
- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, and Kelly Elkins on behalf of KentuckyOne Health request the Cabinet use a statewide use rate in bed need formula instead of the proposed ADD use rate.
 - (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to revert to the statewide use rate in the bed need formula.
- (18) Subject Matter: Provisions regarding Psychiatric Hospital Beds
- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, and Kelly Elkins on behalf of KentuckyOne Health request that critical access hospitals be included in the geriatric psychiatric

services criteria.

- (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to include critical access hospitals in the geriatric psychiatric services criteria.

(19) Subject Matter: Provisions regarding Psychiatric Hospital Beds

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, and Kelly Elkins on behalf of KentuckyOne Health request that the term "allocated beds" be defined.

- (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to define "allocated beds".

(20) Subject Matter: Provisions regarding Psychiatric Hospital Beds

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, and Kelly Elkins on behalf of KentuckyOne Health request that the Cabinet's Psychiatric Bed Calculations on OHP's website be renamed "Bed Cap" instead of "Bed Need".

- (b) Response: The Cabinet has considered this comment and has determined a change to the State Health Plan is not necessary as the change is related to the Cabinet's Psychiatric Bed Calculations on the website.

(21) Subject Matter: Provisions regarding Cardiac Catheterization definition of "therapeutic" catheterization.

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the codes being used to define PCI procedures be revised to remove those that are not PCI (i.e. pacemakers are not a PCI and should not be counted as such).

- (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan. The definition of "therapeutic" does not include any reference to pacemakers or procedures that are not a PCI.

(22) Subject Matter: Provisions regarding Cardiac Catheterization definition of

"procedure".

(a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request the addition of a definition of "procedure" consistent with the manner that the Cabinet counts cardiac catheterization volume.

(b) Response: The Cabinet has considered this comment and will amend the State Health Plan to clearly define how the number of cardiac catheterization procedures is determined.

(23) Subject Matter: Provisions regarding Cardiac Catheterization primary only PCI programs.

(a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the specific standards under Criterion 2 pertaining to primary PCI programs be deleted because The American College of Cardiology (ACC) guidelines now combines primary and elective programs. They also request that the two (2) year "trial period" be removed from the criteria.

(b) Response: The Cabinet has considered this comment and will not amend the State Health Plan as requested. However, the State Health Plan review criteria will be amended to delete the requirement for separate pilot programs for primary and elective PCI. The State Health Plan will be amended to require a two (2) year pilot program for combined primary and elective PCI. This will ensure that appropriate planning for program development has been accomplished and that programs have acceptable annual volumes and risk-adjusted outcomes statistics comparable to those reported in contemporary national data registries in accordance with ACC guidelines.

(24) Subject Matter: Provisions regarding Cardiac Catheterization Therapeutic Criteria

(a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip

Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the language be clarified that the relationship with the tertiary partner should be ongoing for patient referral and that the language be clarified that the joint performance improvement program, joint in-service staff education programs, and joint peer review should only be required for the first two years.

- (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan as requested. The State Health Plan will be amended to delete the requirement for separate pilot programs for primary and elective PCI as stated above. Furthermore, the State Health Plan will be amended to require an ongoing agreement during and after the pilot with the tertiary partner for joint performance improvement program, joint in-service staff education programs, and joint peer review. This will ensure that programs will continue to have acceptable annual volumes and risk-adjusted outcomes statistics comparable to those reported in contemporary national data registries in accordance with ACC guidelines.

(25) Subject Matter: Provisions regarding Cardiac Catheterization Criteria Changes

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the minimum volume requirement for diagnostic catheterizations as a condition to apply for a PCI program be deleted and instead insert the requirement that a diagnostic cardiac catheterization program have operated for at least one year prior to application to expand the program to offer therapeutic catheterization.

- (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan and the requirement for 300 annual diagnostic procedures will be retained to ensure that the proposed PCI program will have acceptable volume. The ACC guidelines do not recommend that elective/urgent PCI be performed by low-volume operators (less than 75 procedures per year) at low-volume centers (300-400 procedures per year).

(26) Subject Matter: Provisions regarding Cardiac Catheterization Criteria Changes

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the

Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the minimum volume performance of at least thirty six (36) primary PCI procedures per year by the end of the second year of operation be deleted, and that the language in Criterion # 3(d) be strengthened to assure that all hospitals approved for a therapeutic program offer primary PCI 24/7.

- (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to remove the minimum volume requirement for primary PCIs as requested. Further revisions are not necessary as the existing language includes the requirement that primary PCI be available on a 24 hour basis.

(27) Subject Matter: Provisions regarding Cardiac Catheterization Criteria Changes

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the minimum PCI volume of the facility's program director be changed from 500 lifetime procedures to require 150 PCI's annually.
- (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan as requested. However, the State Health Plan will be amended to require that in addition to the 500 lifetime procedures, the program director must have performed a minimum of 150 PCIs in the previous year and be board certified by the American Board of Internal Medicine in interventional cardiology. The State Health Plan has also been revised to allow a program director to be located off-site and to require the on-site cardiologist to be board certified by the American Board of Internal Medicine in interventional cardiology.

(28) Subject Matter: Provisions regarding Cardiac Catheterization Criteria Changes

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the plan's current reference to an "ideal" volume of 400 procedures be deleted and retain the program minimum volume of 200 procedures.
- (b) Response: The Cabinet has considered this comment and will not amend the

State Health Plan to delete the language related to "ideal" volume as this language is consistent with recommendations in the ACC guidelines.

(29) Subject Matter: Provisions regarding Ambulatory Surgical Services.

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, and Kelly Elkins on behalf of KentuckyOne Health supports the exclusion of cystoscopy rooms from the number of ASC operating rooms used to calculate inpatient and outpatient operating room utilization so long as all of the procedures performed in those cystoscopy rooms are also excluded from the methodology.
- (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan. Pursuant to 900 KAR 6:155 – Certificate of Need annual surveys, and registration requirements for new Magnetic Resonance Imaging units, facilities submit only those cystoscopy procedures performed in an operating room. The number of procedures performed in a cystoscopy room is not reported. Therefore, the cystoscopy procedures performed in a cystoscopy room have never been collected and have never been considered in the need calculation. The changes to the State Health Plan were made to clarify existing policy.

(30) Subject Matter: Provisions regarding Home Health Services.

- (a) Comment: Brian Lebanon on behalf of Professional Home Health Care Agency and Kip Bowmar on behalf of Kentucky Home Care Association request that the provisions regarding Energy Employees Occupational Illness Compensation Program (EEOICPA) be deleted.
- (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to delete this provision.

(31) Subject Matter: Support for provisions regarding Home Health Services.

- (a) Comment: Greg Austin on behalf of Professional Case Management requests that the provisions regarding Energy Employees Occupational Illness Compensation Program (EEOICPA) be retained.
- (b) Response: The Cabinet has considered this comment however the State Health Plan will be amended to delete this provision regarding EEOICPA as existing providers may provide these services.

(32) Subject Matter: Provisions regarding Private Duty Nursing services to pediatric patients.

- (a) Comment: Brian Lebanon on behalf of Professional Home Health Care Agency requests deletion of the criterion allowing approval of applications for provision of services to pediatric patients.
 - (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan to delete the criterion but will revise the State Health Plan criterion to address consideration of existing providers of services to this population.
- (33) Subject Matter: Provisions regarding Private Duty Nursing services to pediatric patients.
 - (a) Comment: Kip Bowmar on behalf of Kentucky Home Care Association requests that the criterion allowing approval of applications for provision of services to pediatric patients be revised to address consideration of existing providers of services to this population.
 - (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to address consideration of existing providers of services to this population.
- (34) Subject Matter: Provisions regarding Private Duty Nursing services to Model II Waiver patients.
 - (a) Comment: Brian Lebanon on behalf of Professional Home Health Care Agency requests deletion of the criterion allowing approval of applications for provisions of Model II Waiver services to Medicaid patients.
 - (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan to delete the criterion but will revise the State Health Plan criterion to address consideration of existing providers of services to this population.
- (35) Subject Matter: Provisions regarding Private Duty Nursing services to Model II Waiver patients.
 - (a) Comment: Kip Bowmar on behalf of Kentucky Home Care Association requests that the criterion allowing approval of applications for provision of services to Model II Waiver patients be revised to address consideration of existing providers of services to this population.
 - (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to address consideration of existing providers of services to this population.
- (36) Subject Matter: Provisions regarding Nursing Facility Beds.

- (a) Comment: Marie Cull/Marian Hayden on behalf of Boonespring Transitional Care Center requests that language similar to that currently contained in administrative regulation 900 KAR 6:075 – Certificate of Need nonsubstantive review related to the transfer or relocation of existing nursing facility beds in facilities with an inventory of at least 250 beds be included in the State Health Plan.
 - (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan as this issue is currently in litigation.
- (37) Subject Matter: Provisions regarding Intermediate Care Facility for the Mentally Retarded & Developmentally Disabled.
 - (a) Comment: Heidi Schissler Lanham on behalf of Protection & Advocacy requests language be amended to prohibit the transfer of public ICF-MR/DD beds to private entities.
 - (b) Response: The Cabinet has considered this comment and will not amend the State Health Plan at this time. The existing review criteria provides the Cabinet with flexibility necessary to transfer public ICF-MR/DD beds to private ICF-MR/DD facilities without increasing the total number of ICF-MR/DD beds available statewide.
- (38) Subject Matter: Provisions regarding statutory reference in Technical Notes.
 - (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, and Kelly Elkins on behalf of KentuckyOne Health request that the statutory reference under the "Purpose" section regarding determining whether a substantial change to a health services has occurred should be changed to KRS 216B.015(29).
 - (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to change the statutory reference to 216B.015(29).
- (39) Subject Matter: Provisions regarding exclusion of facilities owned or operated by the Commonwealth in the inventory or need calculations in Technical Notes.
 - (a) Comment: Mary Jo Bean on behalf of Norton Healthcare requests that the Provisions regarding exclusion of facilities owned or operated by the Commonwealth in the inventory or need calculations in Technical Notes be clarified regarding which facilities are excluded from the need calculations.

- (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to clarify that only state owned or operated psychiatric or long-term care beds are excluded from the inventory or need calculations.
- (40) Subject Matter: Provisions regarding county or counties used to define a geographic area in Technical Notes.
- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Wade Stone on behalf of The Medical Center, John Dubis on behalf of St. Elizabeth Healthcare, Kelly Elkins on behalf of KentuckyOne Health, Chip Peal on behalf of Frankfort Regional Medical Center, Bruce Begley and the Methodist Hospital board of Directors on behalf of Methodist Hospital, and Kevin B. Halter on behalf of Our Lady of Bellefonte Hospital request that the plan clarify that the planning area is comprised of counties in Kentucky.
- (b) Response: The Cabinet has considered this comment and will amend the State Health Plan to clarify that only counties located within Kentucky may be used to define the geographic area.

Summary of Statement of Consideration and
Action Taken by Promulgating Administrative Body

The Office of Health Policy is amending this administrative regulation in response to public comments received as follows:

Page 1

Section 1

Line 13

After "Section 1. The" insert "2013-2105"

Delete "2012[2014] Update to the 2010-2012"

Page 1

Section 1

Line 17

After "KRS 216B.015", insert (29)

Delete (28)

Page 1

Section 2

Line 18

After "(1) The" insert "2013-2105"

Delete "2012[2014] Update to the 2010-2012"

Page 1

Section 2

Line 19

After "State Health Plan", insert "February 2013"

Delete "November 2012"

Page 2

Section 2

Line 1

After "275 East Main Street," insert "4WE"

Delete "fourth floor"

The Office of Health Policy is amending the material incorporated by reference in response to public comments received as follows:

- a. There were various formatting changes made throughout the document that did not change the content.
- b. The introductory page was changed to reflect the change in dates within the title from the 2012 Update to the 2010 – 2012 State Health Plan (November, 2012) to the 2013 – 2015 State Health Plan and revision date of February 2013.
- c. The Table of Contents on page ii was revised to reflect changes in page numbers as a result of content changes in the document.
- d. Page iii, first paragraph was revised to correctly reference the 2013 – 2015 State Health Plan and to correctly reference statute KRS 216B.015(29).
- e. Page iii, second paragraph was revised to correctly reference statute KRS 216B.015(28).
- f. Page iii, item 1 under technical notes, was revised for clarity.
- g. Page iii, new item 2 was inserted to add language clarifying that only counties located within Kentucky are considered in the geographic area for review. Subsequent items were renumbered.
- h. Page iii, item 4 (now item 3) was revised to add the web site where utilization reports are available and the phone number to contact the Office of Health Policy.
- i. Page iv, item 5 (now item 6) was revised to remove reference to “acute”.
- j. Page iv, item 8 (now item 9) was revised to delete reference to Kentucky Annual Magnetic Resonance Imaging Services Report and a secondary phone number for OHP.
- k. Page iv, item 11 (now item 12) was revised to delete reference to PET/CT scanner.
- l. Page 1, first paragraph under definitions, 6th line, after “Division of Health Care” delete “Facilities”.
- m. Page 2, first line, revised to indicate the correct symbol for multiplication.
- n. Page 7, description for “PD” was revised to indicate beds “statewide”.
- o. Page 9, item 5 was revised to clarify the most recent edition of the American Academy of pediatrics and the American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care is used.

- p. Page 9, item 6 was revised to change the reference from "their" to "the".
- q. Page 10, item 6 d was revised to clarify obstetricians and neonatologists may be on site or able to be present on the unit.
- r. Page 10, item 6 f was revised to clarify that personnel have specialized training in neonatal care.
- s. Page 10, a new item 7 was added to provide review criteria to be used when reviewing an application from an applicant for Level II special care neonatal care beds that will provide care for stable or moderately ill newborn infants who are born at ≥ 28 weeks gestation, or who weigh ≥ 1200 grams at birth, or require ventilation for > 24 hours. The criteria includes establishment of a relationship through a written affiliation agreement with a Level IV facility and the requirements to be included in that agreement, requirement to participate in the Vermont-Oxford Network (VON), demonstrate readily available pediatric ophthalmology services, and consultation from a maternal-fetal medicine specialist. Subsequent items were renumbered.
- q. Page 10, item 7 (now item 8) is revised to clarify notwithstanding only criterion 1 above.
- r. Page 10, item 2 under Level III criteria is revised to clarify the most recent edition of the American Academy of pediatrics and the American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care is used.
- s. Page 11, item 3 b under Level III criteria is revised to clarify neonatologists and personnel have specialized training in neonatal care and be on-site and available 24 hours per day.
- t. Page 11, item 3 c under Level III criteria is reworded for clarification.
- u. Page 11, item 3 j under Level III criteria clarifies the VON report on outcomes of Level III facility is submitted to the Cabinet.
- v. Page 11, new item k was added to clarify that an applicant proposing to establish Level III services requires the establishment of a relationship through a written affiliation agreement with a Level IV facility and the requirements to be included in that agreement.
- w. Page 12, item 4 under Level III is revised to clarify notwithstanding only criterion 1 above.
- x. Page 12, item 5 under Level III is revised to clarify notwithstanding only criteria 1 and 4 above.

- y. Page 12, item 1 under Level IV is revised to clarify the applicant must be an academic medical center or a children's hospital with a pediatric and neonatal training program that is accredited by the American College of Graduate Medical Education.
- z. Page 12, item 3 under Level IV is revised to eliminate reference to an example.
- aa. Page 12, new item 6 is added to clarify the responsibilities of the Level IV facility within the written affiliation agreement with the Level II facility.
- ab. Page 12, new item 7 was added to clarify that the Level IV facility will enter into a written affiliation agreement with the Level III facility.
- ac. Page 12, new item 8 was added to clarify the commitments required of the Level IV facility.
- ad. Page 14, item 1 g last sentence was deleted.
- ae. Page 16, a new definition for "Allocate psychiatric beds" was added.
- af. Page 19, first paragraph under Geriatric Psychiatric Services was revised to include critical access hospitals.
- ag. Page 20, item 1 was revised to clarify reference to acute care hospital.
- ah. Page 20, item 2 was revised to clarify reference to acute care hospital.
- ai. Page 20, item 3 was revised to remove language related to converted beds and remove reference to acute care.
- aj. Page 20, item 4 was revised to remove reference to converted beds.
- ak. Page 20, item 5 was revised to reference applicant rather than hospital.
- al. Page 20, item 7 was revised to reference geriatric psychiatric rather than converted beds.
- am. Page 28, definition of Energy Employees Occupational Illness Compensation Program was deleted.
- an. Page 28, first paragraph under Summary of Need Criteria, the last sentence related to EEOICPA was deleted.
- ao. Page 28, second paragraph under Summary of Need Criteria, the last sentence related to EEOICPA was deleted.

- ap. Page 29, item 4 is deleted.
- aq. Page 35, definition of Cardiac Catheterization, second sentence related to a single procedure was deleted.
- ar. Page 35, definition of Cardiac Catheterization, in third sentence, after "cardiac Catheterization" insert procedures.
- as. Page 35, in the entirety of section "A. Cardiac Catheterization Service", all references to *Annual Administrative Claims Data Report* have been changed to *Annual Administrative Claims Data Report – Cardiac Catheterization*.
- at. Page 36, item 1 a. is revised to delete reference to Facilities.
- au. Page 36, item 2 is revised to insert "and elective" after "(i.e. emergency)".
- av. Page 37, item 2 b, deleted all information after "during the previous two (2) years".
- aw. Page 37, item 2 c was deleted and subsequent subsections were renumbered.
- ax. Page 37, item 2 g (now 2 f) was revised to add unstable angina, and angina that is refractory to medical treatment at the end of the sentence.
- ay. Page 38, item 2 k (now 2 j) was revised to add references to located on-site or based at a facility and added reference that the program director must have performed a minimum of 150 PCI procedures in the previous year.
- az. Page 38, item 2 l (now 2 k) was added to state cardiologist on-site must be board certified by the American board of Internal Medicine in interventional cardiology.
- ba. Page 38, item 2 m i was revised to add "and elective" after "have received primary".
- bb. Page 38, new item 2 n was added to clarify the actions required at the end of the two (2) year trial related to verification of quality of the program.
- bc. Page 38, all of existing item 3 was deleted and subsequent sections were renumbered.
- bd. Page 40, item 4 (now item 3) first sentence was reorganized with subsections a and b for clarity. This necessitated existing subsections a through d being renumbered to i through iv.

- be. Page 40, item 4 a (now item 3 b i) is revised to clarify the applicant must have previously completed the two (2) year pilot for primary and/or elective PCI and have completed the requirements of 900 KAR 6:120.
- bf. Page 40, item 4 b (now item 3 b ii) is revised to clarify the applicant must submit verification of quality as specified in criterion 2.n. above.
- bg. Page 40, item 4 c (now item 3 b iii) is revised to reference item 3.b.iv rather than 4 d.
- bh. Page 40 Item 4 d (now item 3 b iv) is revised to reference the most recent edition of the Administrative Claims Data Report and an average of at least three hundred (300) annual diagnostic cardiac catheterization procedures.
- bi. Page 41, new item 3 b v was added to clarify the applicant will maintain a signed collaboration agreement with a tertiary hospital and what the agreement shall address.
- bj. Page 42, item 6 (now item 5) was revised to reference Level IV rather than Level III.
- bk. Page 56, item 3 was revised to add language that notwithstanding the above criteria and the application must demonstrate the proposed services is not currently provided by another licensed home health agency or private duty nursing service provider.
- bl. Page 56, item 4 was revised add language that notwithstanding the above criteria and the application must demonstrate the proposed services is not currently provided by another licensed home health agency or private duty nursing service provider.
- bm. Page 57, reference to Attachment A is deleted, and the attachment is deleted.